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510(k) Summary of Safety and Effectiveness: VariAx™ Locked Plating System Line Extension for Addition of Fibula Straight Plates

DEC - 7 2010

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430
For Information contact:	Stephanie M. Fitts, Director Regulatory Affairs and Regulatory Compliance Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5405 Fax: (201) 831-4405
Date Summary Prepared:	November 29, 2010

Device Identification

Proprietary Name:	VariAx™ Locked Plating System Line Extension for addition of Fibula Straight Plates
Common Name:	Bone plates and screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 HRS: Plate, Fixation, Bone

Description:

This 510(k) submission is intended to add bone plates with a different geometry to the VariAx™ fibular plate line which was cleared in K081284. The new plates are termed "Fibula Straight Plates" and consist of the shaft portion of the cleared plate plus an oblong screw hole in some configurations. Additionally, other fixation plates (predicates) have been cleared with the approximate plate length of the subject device, including the Synthes 3.5 mm LCP® Medial Distal Tibia Plates (K001945) and Synthes One-Third Tubular Dynamic Compression Locking (DCL) (K011335).

Intended Use:

The VariAx™ Fibula Locked Plating System Line Extension addition of Fibula Straight Plates does not alter the intended use of the predicate system as cleared in K081284. The indications for use for the subject plates are provided below.

Indications for Use:

The VariAx™ Fibula Straight Plates are intended for use in internal fixation of the distal fibula.

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Statement of Technological Comparison:

The subject and predicate devices are made from Titanium Grade 2 with type II anodization. Fatigue strength verification and stiffness analysis were evaluated by way of a 4-point bending test. Median fatigue limits and stiffness of the subject VariAx™ Fibula Straight Plates were found equivalent to the existing fibula plates in the predicate system, Synthes One-Third Tubular Dynamic Compression Locking plates. The data presented demonstrates substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Stephanie M. Fitts
Director Regulatory
325 Corporate Drive
Mahwah, New Jersey 07430

DEC - 7 2010

Re: K102282
Trade/Device Name: Variax™ Fibula Straight Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 05, 2010
Received: November 09, 2010

Dear Ms. Fitts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102282

Indications for Use

510(k) Number (if known): K102282

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Device Name: Variax™ Fibula Straight Plates

Indications For Use:

The VariAx™ Fibula Straight Plates are intended for use in internal fixation of the distal fibula.

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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